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Dated: May 31, 2006 Signature:  (Merlin Aubourg)

Docket No.: BII-001.01
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Roy R. Lobb

Application No.: 10/521,513

Filed: July 17, 2003

For: THERAPIES FOR RENAL FAILURE
USING INTERFERON-BETA-1



Confirmation No.: 2848

Art Unit: N/A

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)) and thus no fees are believed to be due in connection with this submission.

Applicant has not submitted copies of cited U.S. patents or U.S. patent applications. However, Applicant submits herewith copies of foreign and non-patent references. The examiner

should note that since reference BA (WO 01/77137) is over 2,000 pages, it is being provided on CD-R in lieu of a printed paper copy.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

Applicant has also cited for the Examiner's consideration certain co-pending U.S. patent applications. The co-pending applications are listed herewith in accordance with M.P.E.P. § 609.06 which states: "Applicants may wish to list U.S. patent application numbers on other than form PTO-1449 or PTO/SB/08A and 08B format to avoid the application numbers of pending applications being published on the patent. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patented file will reflect that fact as noted in MPEP § 609.05(b)." No copies of the co-pending applications have been provided. If the Examiner wishes to have copies of the co-pending applications, Examiner should contact the Agent of record.

U.S. Application No.	First Named Inventor	Filing Date	Examiner Initials
10/868,673	A. Whitty	06-15-2004	
10/802,540	B. Pepinsky	03-16-2004	
10/892,830	K. Lin	07-16-2004	
10/529,522	A. Sandrock	09-26-2003	
10/095,496	R. Lobb	03-12-2002	
10/397,108	M. Dibiase	03-24-2003	
Examiner Signature:		Date Considered:	

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-1448, under Order No. BII-001.01.

Dated: May 31, 2006

Respectfully submitted,

By *Chad E. Davis*

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Registration No.: 56,179

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Substitute for form 1449A/B/P/T/O

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete If Known

Application Number	10/521,513
Filing Date	July 17, 2003
First Named Inventor	Roy R. Lobb
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	BII-001.01

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	AA*	US-5,908,626		06-01-1999	Chang et al.	
	AB*	US-6,127,332		10-03-2000	Goetz et al.	
	AC*	US-4,588,585		05-13-1986	Mark et al.	
	AD*	US-5,565,335		10-15-1996	Capon et al.	
	AE*	US-6,800,735-A1		10-05-2004	Whitty et al.	
	AF*	US-6,962,978-A1		11-08-2005	Pepinsky et al.	
	AG*	US-6,372,207		04-16-2002	Tepper et al.	
	AH*	US-5,906,816		05-25-1999	Soos et al.	
	AI*	US-6,060,450		05-09-2000	Soos et al.	
	AJ*	US-20030007969-A1		01-09-2003	Lobb et al.	
	AK*	US-20050214253-A1		09-29-2005	Whitty et al.	
	AL*	US-20050107277-A1		05-19-2005	Lin et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	†*
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
	BA	WO-01/77137		10-18-2001			
	BB	WO-00/23472		04-27-2000			
	BC	WO-00/23114		04-27-2000			
	BD	WO-98/28007		07-02-1998			
	BE	WO-04/28472		04-08-2004			
	BF	WO-03/61577		07-31-2003			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with a single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.58(a)(2)(ii)) because that application was filed after June 30, 2003 or is available in the IFW. † Applicant's unique citation designation number (optional). † See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. † Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). † For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. † Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. † Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	†*
	CA	Schwartz, A. et al. "Prophylaxis and Therapy of Severe Lupus Nephritis by Interferon-beta Treatment." Kidney Blood Press. Res. 2001, Vol 24, No. 4-6, p. 218.	
	CB	International Search Report for PCT/US03/22440, mailed July 2, 2004.	
	CC	May and Sehgal. "On the Relationship Between Human Interferon Alpha 1 and Beta 1 Genes." J. Interferon Res. 1985, Vol. 5, p. 521-26.	

Examiner Signature	Date Considered
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PTO/SB/08a/b (07-05)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/521,513		
		Filing Date	July 17, 2003		
		First Named Inventor	Roy R. Lobb		
		Art Unit	N/A		
Examiner Name	Not Yet Assigned				
Sheet	2	of	2	Attorney Docket Number	BII-001.01

CD	N. Kayagaki et al. "Type I Interferons (IFNs) Regulate Tumor Necrosis Factor-related Apoptosis-inducing Ligand (TRAIL) Expression on Human T Cells: A Novel Mechanism for the Antitumor Effects of Type I IFNs." J. Exp. Med. Vol. 189, No. 9, p. 1451-60.	
CE	V.J. Cavanaugh et al. "Inhibition of Hepatitis B virus Replication During Adenovirus and Cytomegalovirus Infections in Transgenic Mice." J. Virol. 1998, Vol. 72, No. 4, p. 2630-37.	
CF	T. Vial et al. "Immune-mediated Side-Effects Of Cytokines In Humans." Toxicology. 1995, Vol. 105, No. 1, p. 31-57.	
CG	J. Imanishi "Interferon-alpha, Beta, Gamma." Gan To Kagaku Ryoho. 1994, Vol. 21, No. 16, p. 2853-58. Abstract.	
CH	T. Ueda et al. "Clinical and Histological Observation of HBV Glomerulonephritis Treated With Interferon-beta." Nippon Jinzo Gakkai Shi. 1990, Vol. 32, No. 11, p. 1153-9. Abstract.	
CI	J.J. Rinehart et al. "Phase I/II trial of Interferon-Beta-Serine in Patients With Renal Cell Carcinoma: Immunological And Biological Effects." Cancer Res. 1987, Vol. 47, No. 9, p. 2481-85.	
CJ	H. Nakayama et al. "Pharmacokinetic Study of Human Natural Beta-Interferon in Patients With End-Stage Renal Failure." Clin. Nephrol. 2001, Vol. 56, No. 5, p. 382-86.	
CK	Y. Shiratori et al. "Different Turnover Rate Of Hepatitis C Virus Clearance by Different Treatment Regimen Using Interferon-beta." J. Hepatol. 2000, Vol. 33, No. 2, p. 313-22.	
CL	S.E. Krown. "Interferon Treatment Of Renal Cell Carcinoma. Current Status And Future Prospects." Cancer. 1987, Vol. 59, No. 3 Suppl., p. 647-51.	
CM	S. Mani et al. "Recombinant Beta-Interferon In The Treatment Of Patients With Metastatic Renal Cell Carcinoma." Am. J. Clin. Oncol. 1996, Vol. 19, No. 2, p. 187-89.	
CN	C. Scoponi et al. "Long-lasting Complete Remission Of Pulmonary Metastases Consequent To Renal Cell Carcinoma Obtained With Interferon-Beta Therapy: Review Of The Literature And A Case Report." Tumor. 1995, Vol. 81, No. 3, p. 201-3.	
CO	E.C. Borden et al. "Biological and Clinical Effects of Interferon-Beta Ser at Two Doses." J Interferon Res. 1990, Vol. 10, No. 6, p. 559-70.	
CP	M. Karpusas et al. "The Crystal Structure of Human Interferon-beta at 2.2-Angstrom Resolution." PNAS. 1997, Vol. 94, pp. 11813-18.	
CQ	F.W.K. Tam et al. "Development of Scarring and Renal Failure in a Rat Model of Crescentic Glomerulonephritis." Nephrol. Dial. Transplant. 1999, Vol. 14, No. 7, p. 1658-66.	
CR	A.R. Allen et al. "Endothelial Expression of VCAM-1 in Experimental Crescentic Nephritis and Effect Of Antibodies to Very Late Antigen-4 or VCAM-1 on Glomerular Injury." J. Immunol. 1999, Vol. 162, No. 9, p. 5519-27.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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